

UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH CAROLINA  
CHARLESTON DIVISION

Joe Patterson,

*Plaintiff,*

Versus

We Are Sharing Hope SC; United Network for  
Organ Sharing; Elizabeth Davies, M.D.;  
Jacqueline Honig, M.D.; and Darla Welker,  
*Defendants.*

) C/A No. 2:21-cv-01242-BHH

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**WE ARE SHARING HOPE SC'S  
MOTION FOR A PROTECTIVE ORDER**

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TO: JOHN C. MOYLAN, III AND LUCY DINKINS, ATTORNEYS FOR THE PLAINTIFF:

Defendant, We Are Sharing Hope SC (hereafter “Sharing Hope” or “this Defendant”), pursuant to Rules 26(c) and 45 of the Federal Rules of Civil Procedure (“FRCP”), moves for the entry of a protective order to protect and prevent Plaintiff from using or relying on materials which were obtained through a subpoena to the United States Centers for Medicare and Medicaid Services (“CMS”) without providing notice to this Defendant pursuant to Rule 45, FRCP.

Some of the documents produced by CMS in response to Plaintiff’s subpoena, which this Defendant had no notice of and therefore could not lodge an objection to, contain materials which are associated with a retrospective, self-critical peer review process conducted by Sharing Hope after the events giving rise to Plaintiff’s claims. Further, some materials produced by CMS in this case were identified on a privilege log in a related case with the same counsel. Had Plaintiff properly provided notice to Sharing Hope of the subpoena at any time over a period of nearly four months<sup>1</sup>, as the rules require, CMS almost certainly would not have produced the privileged

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<sup>1</sup> Based on Plaintiff’s recently filed Motion asking the Court to rule the documents produced by CMS are not privileged, Plaintiff states CMS did not provide documents in response to the subpoena at issue in this case until March 21, 2021 which is four months after the subpoena was issued and well after this Defendant had made a Notice of Appearance (*ECF 57*).

documents in this case. In the absence of Defendant's knowledge of the subpoena served on CMS, the Defendant was not afforded opportunity to object. Had the Defendant been provided notice of the subpoena and the opportunity to object and file motions *before* the documents were provided by CMS, then the materials would not have been produced which has and will significantly and unfairly prejudice this Defendant.

In the present Motion, this Defendant will discuss herein the unique network of federally regulated organ donation and transplantation and the relevant facts as it pertains to Plaintiff's counsel's subpoena practice in this case and in two related cases along with the nature of the privilege Sharing Hope seeks to protect. Moreover, this Motion will discuss that in a related case, the Plaintiff served a subpoena on CMS and did provide the proper notice to this Defendant and CMS did not produce any documents in response to Plaintiff's subpoena.

This matter is related to two other cases currently pending in the Charleston County Court of Common Pleas because all claims arise from the same Donor. Further, some issues raised in the present Motion have also been raised, briefed, and even appealed in one of the related cases. In light of the extensive discovery involving the same issue which has already occurred in the related state court cases, pursuant to Local Civil Rule 7.02, the undersigned counsel certifies that any further attempts to confer with opposing counsel regarding this issue would serve no useful purpose.

### **BACKGROUND ON THE UNIQUE FRAMEWORK AND REGULATION OF ORGAN DONATION**

We are Sharing Hope SC is an Organ Procurement Organization ("OPO") which facilitates the delivery of life-saving organs to persons in need of an organ transplant. Sharing Hope is a South Carolina non-profit corporation and is the federally designated OPO for the State of South Carolina. As South Carolina's OPO, Sharing Hope evaluates potential donors in South Carolina

by hospital referrals and, once a donor is declared to be brain dead, manages the donor to maximize organ function. In this role, Sharing Hope reports and uploads medical information regarding each donor and coordinates organ recovery with the donor hospital and transplant surgeons throughout the United States. In order to understand the complex nature of the Federal regulation encompassing organ donation and transplant and the peer review/quality assurance documents Plaintiff seeks, a discussion of the network of regulation follows.

*Federal Regulation of Organ Procurement Organizations*

In 1984, Congress enacted the National Organ Transplant Act. Pub. L. 98-507, codified as amended at 42 U.S.C. § 273 *et seq.* (2021) (the “Act”). The Act directed the Secretary of Health and Human Services (“HHS”) to create and operate the Organ Procurement and Transplant Network (“OPTN”) for the purpose of establishing a national organ transplant infrastructure to maintain a unified waitlist of individuals in need of such transplants and to assist in the nationwide distribution of organs equitably among transplant patients. 42 U.S.C. § 274(a), (b)(1)(A)-(B), (b)(2)(D); see also United States v. United Network for Organ Sharing, C/A No. 03 C 2295, 2002 WL 1726536, 2002 U.S. Dist. LEXIS 8878 (N.D. Ill. May 17, 2002) (discussing the 1986 contract between HHS and the United Network for Organ Sharing).

As the federally designated OPO for the State of South Carolina, Sharing Hope is a member of the national Organ Procurement and Transplantation Network (“OPTN”). OPOs are a vital part of the OPTN’s organization and operations and are required to be members of the OPTN, 42 C.F.R. § 121.3(b). An entity becomes an OPO by demonstrating its qualifications to the Secretary of HHS and thereafter being designated as a particular region’s OPO by the Secretary or her delegate. 42 U.S.C. § 1320b-8. Only one OPO may be designated for each service area. Id. § 1320b-8(b)(2). In order to be designated as a particular service area’s OPO, an entity must meet

certain qualifications and requirements as outlined in the law, including certification by the Secretary of HHS. *See* 42 U.S.C. § 273.

The OPTN, administered by the United Network for Organ Sharing (“UNOS”), establishes policies which govern the allocation of transplantable organs nationwide; collects clinical data on all transplant candidates and organ donors in the United States; establishes a network of membership requirements for transplant hospitals and OPOs; and monitors their compliance with the established standards, policies, and transplant quality.<sup>2</sup> In order to serve as the South Carolina OPO for UNOS, Sharing Hope must meet and abide by OPTN policies, procedures, standards and requirements as administered by UNOS. For example, UNOS operates the OPTN Membership and Professional Standards Committee (“MPSC”) which maintains membership criteria and monitors member compliance based on OPTN membership criteria, bylaws, and policies. The MPSC conducts peer review of OPTN members and reviews events identified as a risk to patient safety, public health, or the integrity of the OPTN.

*Organ Donation in the Present Matter*

This case arises from a liver transplant provided to Plaintiff Joe Patterson from a South Carolina donor (“the Donor”) whose organs were managed by Sharing Hope. The Donor whose liver was given to Mr. Patterson also gave her lungs for transplant to Allen B. Holliman and her heart to Ykeiah Lawrence (two related cases). The details of the procurement and management of the deceased Donor’s organs and the medical treatment provided to each transplant recipient are not necessary to evaluate the legal issues presented in this Motion, but they are briefly described in this Defendant’s 26.03 disclosures and involve ABO incompatibility. (*ECF* 39-3)

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<sup>2</sup> <https://optn.transplant.hrsa.gov/members/member-actions/>

As a result of Mr. Patterson’s transplant and the transplants in the related cases which all involved the Donor’s organs, and due to the policies established by UNOS pursuant to 42 C.F.R. § 121.10, Sharing Hope and the Membership and Professional Standards Committee (“MPSC”) (operated by UNOS) engaged in a self-critical quality assurance and peer review evaluation the contents of which are protected by applicable peer-review statutes in South Carolina and Virginia as well as by the bylaws of the OPTN promulgated under federal regulation. Indeed, correspondence issued by UNOS in furtherance of this evaluation was labeled “confidential medical peer review”.

The related cases are: The *Holliman* (lungs) case and the *Lawrence* (heart) case. These cases are currently pending in the Charleston County Court of Common Pleas and captioned as follows:

- *Michelle Cha Holliman, individually and as personal representative of the Estate of Allen B. Holliman v. We Are Sharing Hope SC, Medical University of South Carolina, United Network for Organ Sharing, Jacqueline Honig, M.D. and Darla Welker*, C/A No. 2020-CP-10-02902; and
- *Ykeiah Lawrence and Miles Lawrence v. We Are Sharing Hope SC, United Network for Organ Sharing, Atrium Health, Inc., Jacqueline Honig, M.D., Karl Welke, M.D., and Darla Welker* C/A No. 2021-CP-10-02033

The Plaintiffs in the present matter (*Patterson*), the *Holliman* matter, and the *Lawrence* matter are all represented by the same counsel, and this Defendant is also represented by the same counsel in all three cases.

#### *CMS’s Complaint Survey & Investigation*

On or around May of 2019, CMS presented to Sharing Hope a “complaint survey” to determine whether Sharing Hope had maintained compliance with the Social Security Act applicable to OPOs and the Conditions for Coverage for Organ Procurement Organizations. *See* 42 C.F.R § 486.301, *et seq.* During the course of its investigation, CMS met with Sharing Hope’s

staff, and Sharing Hope provided the documents requested by CMS, including certain peer review materials<sup>3</sup>, and quality assurance materials of which some do not pertain to the Donor at issue in the South Carolina case. Sharing Hope also submitted a plan of correction and other documents to CMS which have been produced in the *Holliman* case. Following its review of the documents supplied by Sharing Hope during the investigation, CMS determined that, by July 1, 2019, Sharing Hope had attained substantial compliance with the requirements of the Social Security Act applicable to OPOs and the Conditions for Coverage for Organ Procurement Organizations found at 42 C.F.R § 486.301, *et seq.* Plaintiff's subpoena sought the file regarding the complaint survey in May of 2019 and all follow up and communications.

### **RELEVANT FACTS TO THIS MOTION**

In order to understand the issues presented in the present Motion, a brief discussion of the discovery practice that has occurred in the related *Holliman* and *Lawrence* matters is necessary. Sharing Hope has long suspected that documents produced or obtained under the caption of one case have been, are being, and will be used to further the objectives of each of the three cases. While this may not be problematic with respect to non-privileged or non-confidential discoverable materials and may be encouraged in the light of judicial efficiency, the prejudice experienced by Sharing Hope when privileged or improperly obtained materials are used by Plaintiff's counsel across all three cases is tripled.

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<sup>3</sup> As a general rule, providing peer review privileged material to an investigating governmental agency, in a disciplinary proceeding, or to an accrediting body does not waive the privilege. *See* O.C.G.A. § 31-7-133 (a); S.C. Code Ann. §§ 40-71-20(c) and 44-7-392(5)-(6); Va. Code Ann. § 801-581.17(f),(g), and (i).

*Discovery in Related Cases*

Extensive discovery has already occurred in the *Holliman* matter. Counsel for Plaintiff has pursued, and ultimately received, discovery of the factual information relating to the organ transplant at issue in addition to the usual medical records generated in the course of the treatment of the transplant recipients. For example, Plaintiff's counsel has sought the production of medical records of the Donor, a non-party in this case without authorization, to which Sharing Hope objected and filed a motion based on the production violating the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA provides both criminal and civil penalties if its provisions are violated. Following a hearing, Sharing Hope produced the medical records of the Donor pursuant to Court Order, as required because the Donor is not a party and had not consented to the same.

In addition to the Donor's actual medical records, in the related *Holliman* litigation, Sharing Hope has produced over 1,800 documents including the organ medical record (of the Donor), Sharing Hope policies and procedures, the audit detail, non-privileged emails exchanged on the Sharing Hope email server, and copies of text messages between Sharing Hope employees who were involved in the Donor case when the Donor's blood type was reported. These productions have been made in addition to Sharing Hope's numerous responses to written discovery served on it in the related cases.

Yet Sharing Hope's production of discoverable material was not enough. In the *Holliman* case, counsel for Plaintiff has doggedly pursued the production of the communications and materials exchanged by Sharing Hope and the MPSC, operated by UNOS, during a self-critical quality assurance and peer review evaluation conducted following the management of the Donor common to all three Plaintiffs, as well as a Root Cause Analysis generated pursuant to a meeting

with the Donor Hospital and Sharing Hope. Sharing Hope properly and clearly identified these materials on its privilege log in the *Holliman* matter and objected to producing the same on the basis of the peer review protection. Specifically, the withheld materials consist of those documents and correspondence exchanged between Sharing Hope (the OPO for South Carolina) and the MPSC (the national committee of the OPTN administered by UNOS) while these entities engaged in their confidential peer review process and the root cause analysis with the Donor Hospital.<sup>4</sup>

Sharing Hope's assertion of peer review privilege in the *Holliman* case has resulted in myriad challenges by counsel for Plaintiff. On behalf of their client in *Holliman*, Plaintiff's counsel first challenged Sharing Hope's peer review assertion by filing a motion to compel on November 18, 2020. Before this motion could even be heard, Plaintiff's counsel filed a second motion to compel in *Holliman* seeking the same materials on the same basis. The trial-level order regarding the first motion is currently on appeal to the South Carolina Court of Appeals<sup>5</sup> with a writ of certiorari to the South Carolina Supreme Court.

Despite Sharing Hope's assertion of peer review privilege solely in relation to its post-incident, self-critical evaluation conducted with UNOS' MPSC, Plaintiff's counsel has asked questions in the *Holliman* matter about Sharing Hope's peer review activities to no fewer than four witnesses during discovery depositions taken *after* the initial motions practice and the Notice of Appeal relating to this issue. The insistence on inquiry into this area by Plaintiff's counsel has, unfortunately, required Sharing Hope to instruct each of these witnesses not to answer questions

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<sup>4</sup> To the extent that these communications contain attachments or enclosures of the transplant recipients' medical records, the Donor's medical records, standard operating policies of Sharing Hope, or other records kept in the ordinary course of business, such materials have already been separately produced to the Plaintiff's counsel.

<sup>5</sup> Both Sharing Hope and UNOS appealed the trial court ordering privileged materials to be produced in the *Holliman* case on May 5, 2021. Final briefing was completed on December 9, 2021.



on this topic and to file at least seven motions for protective orders in the *Holliman* matter to protect its privilege assertion; several during the pendency of the appeal.

Thankfully, on November 5, 2021, the Charleston County Court of Common Pleas ordered that all discovery as it relates to the peer review process and documents withheld by Sharing Hope be stayed pending the outcome of the appeal.

*Plaintiffs Acquired Privileged Materials through Improper Subpoena Practices*

In this case, Plaintiff filed his Notice of Intent to Sue on October 22, 2020 and served Sharing Hope by process server on October 29, 2020.<sup>6</sup> While this case was pending under the Notice of Intent phase, and *after Plaintiff served Sharing Hope with the Notice of Intent*, Plaintiff served four subpoenas<sup>7</sup> on non-parties pursuant to Rule 45 of the Federal Rules of Civil Procedure seeking documents relating to Sharing Hope and UNOS without complying with Rule 45's notice requirements.<sup>8</sup> These improper subpoenas were directed to (1) the United States Centers for Medicare and Medicaid Services ("CMS"); (2) the United States Department of Health and Human Services ("HHS"); (3) DCI Donor Services, Inc.; and (4) Dialysis Clinic, Inc. The subpoenas

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<sup>6</sup> Despite having full knowledge of Sharing Hope's representation by the undersigned in a related case (*Holliman*), Plaintiff nevertheless elected to serve Sharing Hope with the Notice of Intent directly by serving the registered agent. Then, on November 17, 2020, Plaintiffs' counsel reached out to the undersigned inquiring if they would also be representing Sharing Hope in the Patterson matter and asked to set a pre-suit mediation. The undersigned had been engaged in litigating the *Holliman* matter for some time.

<sup>7</sup> The exact date of service of these subpoenas was unknown to this Defendant until Plaintiff filed a Motion for Clarification that the CMS documents were not privileged on December 21, 2021. (*ECF 57*). This Defendant had previously asked for this information but it was not provided by the Plaintiff.

<sup>8</sup> The above subpoenas all appear to be issued after service of the Notice of Intent to File Suit on We Are Sharing Hope SC on October 29, 2020 (*See ECF 5-1*). Even though no attorneys had filed an appearance for Sharing Hope prior to the issuance of the subpoenas, the Plaintiff was still required to provide notice to Sharing Hope pursuant to Rule 45, FRCP. Plaintiff's counsel did not reach out prior to the issuance of the subpoenas, nor did Plaintiff's counsel provide the subpoenas to counsel for Sharing Hope when he inquired about Sharing Hope's representation and pre-suit mediation.

sought information and communications with or regarding Sharing Hope, UNOS, and the non-party Donor identified as AFKY 198, 2018-0516, and 18-15828. (*ECF-57-2, ECF 57-3*)

Because the Plaintiff failed to provide this Defendant with prior notice of the subpoenas as required by Rule 45, Sharing Hope did not learn of the four subpoenas issued in *Patterson* during the autumn of 2020 until over four months later, on or about March 23, 2021, just prior to a joint mediation of all three related cases. In an email on March 23, 2021, Plaintiff's counsel disclosed their improper subpoena practice and claimed that they had inadvertently failed to provide Sharing Hope with the required notice of the four subpoenas (*ECF 57-6*). Plaintiff provided what appeared to be some of the documents obtained from the improper subpoenas to the mediator prior to joint mediation. (*ECF 57-7*).

After learning of this of Rule 45 violation, Sharing Hope attempted to investigate and identify the parameters of the dissemination of the improperly acquired documents by Plaintiff's counsel. Sharing Hope has specifically asked Plaintiff to provide the following: (1) the entity served with the subpoena, (2) the date it was issued, (3) the date Plaintiff provided notice of the subpoena to all counsel (if this occurred), (4) whether any documents or other materials were received in response to the subpoena, (5) if documents or other materials were received, the Bates stamps of the documents as they have been produced, and (6) the identity of every person or entity who has been provided with any materials received in response to a subpoena which was not properly noticed as required by Rule 45<sup>9</sup> (*ECF 57-8 and (57-10)*). However, Plaintiff has never

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<sup>9</sup> Sharing Hope sent correspondence to Plaintiff's counsel in all three cases. As Plaintiff points out in their Motion for Clarification that Documents Produced by non-Party Subpoena Recipient United States Centers for Medicare & Medicaid Services are Not Privileged (*ECF 57*). Sharing Hope referred to South Carolina law mistakenly in the case at bar and sent email correspondence to Plaintiff indicating the same. Notably, the provisions of Rule 45(a)(4) SCRPC and Rule 45 (a)(4), FRCP provide notice to each party must be provided before serving on the person to whom the subpoena is directed.

responded to Sharing Hope's request for additional information regarding these improper subpoena practices or the full extent of the use of materials received from the same.<sup>10</sup> In fact, the only documents relating to the four subpoenas served without notice to Sharing Hope as referenced above were the subpoenas absent of any correspondence or indication as to when or on whom they were served. Plaintiff's recently filed Motion for Clarification provides much additional information which Plaintiff's counsel never provided to this Defendant. (ECF-57)

Sharing Hope identified that a portion of the materials provided to Plaintiff by CMS were, in fact, protected peer review materials originally generated and exchanged between Sharing Hope and UNOS' MPSC and the Root Cause Analysis with the Donor Hospital. When CMS performed a survey of Sharing Hope in May of 2019, CMS asked for and Sharing Hope was required to provide these materials to CMS as part of its investigation, but in no way intended to waive its privilege in complying with the law. By letter dated April 6, 2021, Sharing Hope objected to this improper subpoena practice and demanded that the materials received from the same be treated as confidential under the applicable Confidentiality Order entered in this case (ECF 57-10).

*Plaintiff's Improper Acquisition of Sharing Hope's Peer Review Privileged Materials  
Significantly Prejudices this Defendant in All Three Related Cases*

Had Sharing Hope appropriately received notice of Plaintiff's subpoenas, as it is entitled and required to receive under Rule 45, FRCP, Sharing Hope would have had an opportunity to

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<sup>10</sup> This is not the first time Sharing Hope has identified improper subpoena practices by counsel for Plaintiff in the three related cases (*Holliman*, *Lawrence* and *Patterson*). For example, as early as August 19, 2019, on behalf of Plaintiff Holliman, counsel for Plaintiff served a subpoena to the United Network for Organ Sharing (at the time a non-party) without providing notice to Sharing Hope. After Sharing Hope identified this violation of Rule 45 of the South Carolina Rules of Civil Procedure, counsel for Plaintiff provided assurances that Sharing Hope would be copied on future subpoenas. In short, it appears that Plaintiff's counsel is engaging in a pervasive practice of issuing subpoenas without providing Sharing Hope any notice as required by Rule 45 or an opportunity to object or seek a protective order in advance of documents being produced.

object to the production of its peer review protected materials, and based on the response by CMS in the *Holliman* case, these materials would never have been produced. Had Plaintiff's followed the applicable rules, this Defendant would not have had to exhaust significant time and resources in investigating the unfair consequences of the violation and attempting to remedy the situation on its own before needing this Court's assistance. This Defendant should have been given the opportunity object and then if the materials were produced to seek an appropriate protective order with the Court *prior* to Plaintiff having any opportunity to review, analyze, distribute, copy, and limitlessly use these materials. However, due the sequence of events described above, and its pattern of improper subpoena practices, Plaintiff has had every opportunity to (a) analyze and evaluate the portion of Sharing Hope's protected peer review materials contained in the CMS production; (b) to disseminate these materials without the safeguard of an appropriate confidentiality designation; and even (c) to provide these materials to experts for review and consideration as they form their opinions. All of this is prejudicial to Sharing Hope in regards to materials it has claimed as privileged.

*Additional Improper Subpoena Practices Under Toughy*

Following Plaintiff's email regarding their inadvertent failure to provide notice to this Defendant that they were seeking materials from CMS in March of 2021, Plaintiff's counsel then for the first time provided copies of the subpoenas to the four non-parties including both CMS and HHS (*ECF 57-3*). CMS is a division of the Department of Health and Human Services (HHS), to whom Plaintiff also served a subpoena in this case.

These subpoenas provide no assurances that Plaintiff complied with *Touhy* regulations<sup>11</sup> when serving the subpoenas, as detailed in the following paragraph. In fact, HHS's response to Plaintiff indicates that "No Department employee may provide testimony or produce documents in private litigation concerning information acquired in the course of performing official duties unless authorized by an agency head based on a determination that compliance with the request would promote the objectives of the Department." 45 C.F.R. 2.3. (See Exhibit 1). The same would be true of CMS and it does not appear that Plaintiff complied with these regulations to either CMS or HHS, but we also do not have all the documents Plaintiff may have provided to either entity.

A request for documents from a government agency must follow the requirements of *Touhy* for the agency to even consider the request. If the request is proper under *Touhy*, the government agency must then follow its own procedure under *Touhy* to process the request and determine how much, if any, of the requested material to produce. Specifically, CMS's guidelines provide:

"For any surveyor worksheets and notes that are responsive to the subpoena that are forwarded to the CMS RO, *indicate whether the SA believes that release of these records would be a deterrent to future free exchanges of information within the SA because survey personnel will fear public disclosure of their opinions, advice, analyses, and recommendations, and such fear would impinge upon the ability of the surveyor to do his/her job.* (Note that if the SA does not communicate disclosure concerns regarding the release of surveyor worksheets and notes, the CMS FOIA Officer may exercise his discretionary authority to release such documents even if they are protected by a FOIA exemption). If the SA recommends release of surveyor worksheets and notes, this should also be noted in the SA's transmittal letter."<sup>12</sup> Pursuant to 45 C.F.R. Part 2, "Whenever a subpoena duces tecum has been served upon an HHS employee or former employee commanding the production of any record, such person shall refer the subpoena to the Office of the General Counsel (including regional chief counsels) for a determination of the legal sufficiency of the subpoena, whether the subpoena was properly served, and whether the issuing court or other tribunal has jurisdiction over the Department.) If the

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<sup>11</sup> The term "*Touhy* regulations" derives from the Supreme Court's decision in *United States ex rel. Touhy v. Regan*, 340 U.S. 462 (1951), which held that a federal agent could not be held in contempt for failing to produce documents.

<sup>12</sup> Center for Medicaid and State Operations/Survey & Certification Group Memorandum from the Director of the Survey and Certification Group and Director of the Freedom of Information Group to the State Survey Agency Directors (Oct. 2, 2009)(on file with CMS).

General Counsel or his designee determines that the subpoena is legally sufficient, the subpoena was properly served, and the tribunal has jurisdiction, the terms of the subpoena shall be complied with unless affirmative action is taken by the Department to modify or quash the subpoena in accordance with Fed. R. Civ. P. 45 (c). (b) If a subpoena duces tecum served upon an HHS employee or former employee commanding the production of any record is determined by the Office of the General Counsel to be legally insufficient, improperly served, or from a tribunal not having jurisdiction, such subpoena shall be deemed a request for records under the Freedom of Information Act and shall be handled pursuant to the rules governing public disclosure established in 45 CFR part 5.”<sup>13</sup>

As a FOIA request, the subpoena to CMS is subject to certain exemptions under 45 CFR § 5.31. Specifically, Sharing Hope contends the requested information is exempt under subsection (c): “Exemption 3 authorizes our agency to withhold records which are specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b)) provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or establishes particular criteria for withholding or refers to particular types of matters to be withheld; and if enacted after the date of enactment of the OPEN FOIA Act of 2009, October 28, 2009, specifically cites to 5 U.S.C. 552(b)(3).” As explained earlier, Sharing Hope has asserted, and maintains, that its peer review materials and determinations are privileged under applicable South Carolina law (S.C. Code § 40-71-20 and/or § 44-7-392), Virginia Law (UNOS is subject to Virginia law, federal regulation and public policy because these self-evaluative and deliberative materials were created during a retrospective, self-critical quality assurance and peer review evaluation required by UNOS in connection with its management of the donor common to all three of the cases filed by Plaintiff’s counsel. Some of these protected materials were provided to CMS at CMS’s request during a survey of Sharing Hope following the events of this case. If Sharing Hope was provided with prior notice of this subpoena, then Sharing Hope would have immediately notified CMS that some of the materials contained in their file contain privileged materials as it

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<sup>13</sup> 45 C.F.R. Part 2 § 2.5 Subpoenas duces tecum.

did just this in a related case (*Holliman*) and those materials in this case almost certainly would not have been produced.

### **ARGUMENT**

**I. The Court Should Enter a Protective Order to Remedy the Prejudice Suffered by this Defendant in All Three Related Cases as a Result of Plaintiff's Improper Subpoena Practices and to Appropriately Address Plaintiff's Acquisition and Ostensible Use of Sharing Hope's Privileged Materials.**

Sharing Hope's self-critical, retrospective analysis conducted as required by UNOS' MPSC and the Root Cause Analysis between Sharing Hope and the Donor Hospital is protected by the peer review privilege and should not be an area of investigation, or a basis for experts to rely upon, during discovery or trial. In addition to these materials being entitled to protection under applicable peer review statutes and law, these materials should not be available to Plaintiff in this case as a result of Plaintiff's improper subpoena practices. The Court should enter an appropriate protective order prohibiting further attempts to discover, use, or disseminate materials or information related to Sharing Hope's peer review activities during any future chapter of this case including both discovery and trial.

**A. Sharing Hope is Entitled to a Protective Order Pursuant to Rule 45 to Remedy Plaintiff's Improper Subpoena Practices.**

***1. Plaintiff's Subpoena to CMS Violated Rule 45, FRCP***

Rule 45(a)(4) of the Federal Rules of Civil Procedure provides, "[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then *before* it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party" (emphasis added). The rule requires that the party issuing the subpoena must provide notice to all the parties in litigation prior to serving the subpoena on the non-party. Here, the Plaintiff did not provide any notice to this

Defendant after they were served with the Notice of Intent, when this Defendant's counsel made an appearance, nor at any other time in the four months until the documents were provided to this Defendant.

The purpose of the requirement of prior notice to the parties "is to afford other parties an opportunity to object to the production or inspection, or to serve a demand for additional documents or things." Rule 45, FRCP, Notes of Advisory Committee on Rules. "[C]ompliance with the notice provision is not a mere formality but serves the important function of streamlining discovery in order to alleviate duplication or delays." Callanan v. Riggers & Erectors, Inc., 149 F.R.D. 519, 520 (D.V.I. 1992), Potomac Elec. Power Co. v. Elec. Motor Supply, Inc., 190 F.R.D. 372, 379 (D. Md. 1999). "When a party fails to receive prior notice of the information sought from a non-party, a party is deprived of its greatest safeguard under the Rule, that is, the ability to object to the release of the information prior to disclosure." Spencer v. Steinman, 179 F.R.D. 484, 489 (E.D. Pa.1998). "In addition, when an attorney misuses his or her power under Rule 45 to command a non-litigant to produce documents in a lawsuit to which he or she is a stranger by failing to give appropriate notice to the parties, public confidence in the integrity of court processes is eroded." Spencer, 179 F.R.D. at 489.

In Solais v. Vesuvio's II Pizza & Grill, Inc., the court quashed the non-party subpoenas because in that case, the Defendants failed to comply with Rule 45(a)(4)'s prior notice requirement. (Citing F.D.I.C., 2015 U.S. Dist LEXIS 104517, 2015 WL 4744361, at 3 stating "Because plaintiff failed to provide prior notice of the Subpoena, as required by Rule 45(a)(4), the Subpoena is void and unenforceable.") See also, Martinez v. Target Corp., 278 F.R.D. 452, 453 (D. Minn. 2011) (rejecting argument that plaintiff was not prejudiced by defendant's failure to comply with Rule 45(a)(4) because the prejudice to the plaintiff was anticipated by the existence of Rule 45 (a)(4).



Pursuant to Rule 45, FRCP, when opposing counsel has notice and sufficient time to object, then they are not prejudiced by a violation of the Rule 45 notice requirement.

In Murphy, the court quashed twelve subpoenas and directed counsel to turn over all of the documents that it had been provided in response to the subpoenas. Murphy v. Board of Educ., 196 F.R.D. 220. The potential harm from violations of subpoena practice were addressed by the Court in Spencer v. Steinman, 179 F.R.D. 484, 489 (E.D. Pa. 1998)(vacated in part) wherein the court stated:

The risks attached to misuse of the subpoena power are great. Under this delegation of public power, an attorney is licensed to access, through a nonparty with no interest to object, the most personal and sensitive information about a party. By failing to receive prior notice of the information sought from the nonparty, a party is deprived of its greatest safeguard under the Rule, i.e., the ability to object to the release of the information prior to its disclosure. Therefore, the loss of the opportunity to object prior to the release of the information caused injury to Defendant. Moreover, misuse of the subpoena power is not limited to the harm it inflicts upon the parties, it also compromises the integrity of the court's processes. When the power is misused, public confidence in the integrity of the judicial process is eroded. Therefore, the failure to provide prior notice to Defendant of the subpoenas cause[s] injury to the public.

In the case at bar, CMS produced documents which Sharing Hope contends are privileged. Sharing Hope was not provided an opportunity to object, and moreover, when Sharing Hope was afforded the opportunity to object in a related case and provide notice to CMS that Plaintiff sought documents Sharing Hope contends are privileged, CMS did not produce any documents. This demonstrates that if the Plaintiff had complied with the rules and Sharing Hope was able to object to the subpoenas at issue, CMS almost certainly would not have produced the privileged material. Thus, Plaintiff's violation of the rule led to CMS's inadvertent production of privileged material and significant prejudice to Sharing Hope in all three cases. As noted earlier, the production of this privileged material without Sharing Hope's knowledge has given Plaintiff ample opportunity to review, analyze, distribute, and apply this material almost limitlessly to all three related cases.

Specifically, Plaintiff may have provided this material for its expert witnesses to base their opinions on. Defendant was unable to take action in the manner in which Rule 45, FRCP contemplates and it has exhausted significant time and resources in an effort to identify the scope of the issue and remedy the prejudice already caused. Without the assistance of this Court, Sharing Hope will continue to be prejudiced in all three cases due to Plaintiff's improper subpoena practices resulting in the unfair acquisition of privileged material.

In citing the 1991 Advisory Committee Notes to Rule 45, noting that the purpose of the notice requirement is to provide opposing parties an opportunity to object to the subpoena, the United States Court of Appeals for the Tenth Circuit affirmed that where an attorney failed to serve the opposing party with prior notice of three subpoenas, he violated Rule 45 of the Federal Rules of Civil Procedure. Butler v. Biocore Med. Techs., Inc., 348 F.3d 1163, 1173 (10th Cir. 2003) (the Court also affirmed that in repeatedly violating Rule 45 FRCP, although ignorantly, the attorney also violated the Kansas Model Rules of Professional). Although the specific allegation was that the attorney violated Fed. R. Civ. P. 45(b)(1) as opposed to Rule 45(a)(4), it noted that the attorney violated the rule "requiring notice to all parties of subpoenas." Id. At 1165. The Court's rationale that "[f]or an objection to be reasonably possible, notice must be given well in advance of the production date" would also apply to Rule 45(a)(4). Finally, the Court held that despite mistake, ignorance, or other excuse for the violation, it also amounted to a violation of the state's ethical rules. Id.

The same rationale applies here. Without *prior* notice, (or in this case any notice until the documents were produced four months later), of the subpoena to Counsel for Sharing Hope, it was not reasonably possible for Sharing Hope to object to the subpoena or take any measure to protect its privileged documents sought after in the subpoena to CMS. Depriving Sharing Hope of its

opportunity to object or protect its privileged documents caused them great prejudice as Sharing Hope was unable to take any action before CMS produced a significant amount of Sharing Hope's privileged materials.

While many of the cases on this issue before the district courts involve a factual scenario where opposing counsel has discovered the rule violation before privileged documents were inadvertently produced, these courts recognize the possibility of prejudice in the event opposing counsel hadn't discovered the subpoena or rule violation. *See Phillips v. Ottey*, Civil Action No. DKC 14-0980, 2016 U.S. Dist. LEXIS 154478, at \*12 (D. Md. Nov. 7, 2016) (internal citations omitted) ("Upon a finding that notice was not given, courts can either strike the subpoenas or allow the affected parties the opportunity to object. Delayed service alone, however, is not a basis to quash a subpoena. The objecting party must also demonstrate prejudice."); *Keller v. Arrieta*, No. 20-259 KG/SCY, 2021 U.S. Dist. LEXIS 139536, at \*8-9 (D.N.M. July 27, 2021) ("Because no documents have been produced in response to the subpoena and because the Court stayed enforcement of the subpoena until the present motion to quash is resolved, Keller has suffered no prejudice as a result of the prior notice failure."); see also *Potomac Elec. Power Co. v. Elec. Motor Supply, Inc.*, 190 F.R.D. 372, 380 (D.Md. 1999) ("When a party fails to receive prior notice of the information sought from a non-party, a party is deprived of its greatest safeguard under the Rule, that is, the ability to object to the release of the information prior to disclosure.").

The present matter is distinguished factually in that Sharing Hope was and still is significantly prejudiced because its privileged documents were produced *as a direct result of the Rule 45 violation*. These documents contain privileged information applicable to the three cases connected to this Donor tripling the harm to Sharing Hope. Moreover, if this Court does not remedy the issue at hand, opposing counsel would essentially be rewarded for its pattern of

improper subpoena practices with access to this information it would not have been able to access absent its rule violation.

Most significantly, in 2019 this Court found the following instructive:

Rule 45 requires that before [a subpoena] is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party. Fed. R. Civ. P. 45(a)(4). Serving a subpoena requires delivering a copy to the named person”....” Fed. R. Civ. P. 45(b)(1)...District courts in the Fourth Circuit have confirmed that service is effective under Rule 45 once a Party uses means reasonably sure to complete delivery[,] including via FedEx. Bland v. Fairfax Cty., Va., 275 F.R.D. 466, 471 (E.D. Va. 2011). Therefore, here, where the subpoenas were mailed via FedEx as of 7:02 pm on April 22, 2019, but Plaintiff did not receive notice until 7:44 pm, Defendant failed to provide Plaintiff with prior notice. (Dkt. Nos. 73-3; 73-4.)

However, even though Defendant's conduct was a technical violation of the rule, the Court finds it would be inappropriate to quash the subpoenas as there was no prejudice to Plaintiff because he received over two weeks’ notice prior to the return date and was able to file a motion to quash Epstein v. Town of Bluffton , No. 9:19-2251-DCN-BM, 2019 U.S. Dist. LEXIS 241099, at \*2-3 (D.S.C. Nov. 5, 2019)(internal citations and quotations omitted).

Like the other district court cases on Rule 45 violations, the issue in Epstein was caught before privileged materials could be produced (“while Plaintiff did not receive prior notice, he did receive notice prior to the return date and was able to file this motion to quash prior to USCB producing any documents.”) Id. at 4. The Court noted, however, “the prejudice in this case derives from the fact that the subpoena was sent to [Plaintiff’s] current employer before he had an opportunity to object, which (Plaintiff contends) could now jeopardize his current job, prejudice which is not cured by Plaintiff being able to now contest compliance with the subpoena before any material it seeks is provided.” Id. Thus, in recognizing this form of prejudice, the Court held “Plaintiff should have been provided with notice sufficient for him to have been able to take some

responsive action (if such was desired) before the subpoena was sent.” In finding that some of this material sought was not within the scope of discovery, it granted Plaintiff’s Motion to Quash in part with respect to this material. Id at 6. Moreover, it granted Plaintiff’s Motion for a Protective Order “to prohibit the Defendant from further issuing ‘improper’ subpoenas. Id at 8.

While the facts are distinguishable from the present matter, this Court demonstrated in Epstein that it recognizes the harmful prejudice that could result from a Rule 45 violation and recognizes Protective Orders as appropriate remedies to this violation. As Sharing Hope can demonstrate significant prejudice in this matter as a result of the Rule 45 violation, this Court, in accordance with Epstein, should grant Sharing Hope’s Motion for Protective Order as a minimum remedy.

***2. Plaintiff’s Subpoena to CMS Failed to Comply with Applicable Federal Law, Federal Regulation, and CMS’ Agency Guidelines***

Federal statute, regulation, and CMS internal guidelines provide specific guidance on the scope of information and materials which may be provided in response to subpoena or FOIA requests served on federal agencies such as CMS (*E.g.*, 42 U.S.C. § 299b-22; 42 CFR §§ 401.101–401.152; CMS Memo, S&C-10-01-ALL, Oct. 2, 2009). Further, CMS is obligated as a matter of law to withhold many of the materials which were ultimately produced. By way of example, patient safety work product such as the materials produced by CMS in response to Plaintiff’s subpoena is specifically protected from disclosure and should not be produced. *See, e.g.*, Patient Safety Improvement Act, 42 U.S.C. § 299b-21 *et seq.*; *Quimbey v. Comm. Health Sys. Prof. Servs. Cor.*, 222 F. Supp. 3d 1038 (D.N.M. 2016).

As explained in the previous section, We Are Sharing Hope SC received no notice of Plaintiff’s subpoena as required by Rule 45(a)(4), FRCP and this failure resulted in We Are Sharing Hope SC losing any opportunity to object to the service of the CMS subpoena or to move for a protective

order prior to Plaintiff, or any other party, receiving and reviewing materials which are protected under the law. As discussed *supra*, in a related case, Sharing Hope did object to a subpoena to Kathy Brazil (investigator) at CMS for her testimony and her deposition along with filing a Motion to Quash in both South Carolina and Georgia. At this juncture, it appears these materials obtained by subpoena were used to prepare for mediation, to serve additional discovery in the related case, and may have even been provided to Plaintiff's experts.

Thus, not only did Plaintiff's improper subpoena practices violate Rule 45 FCRP, but they were also improper under *Toughy* regulations for subpoenas FOIA requests. In issuing the subpoena to CMS, Plaintiff acted improperly in two different ways, both of which resulted in it unfairly acquiring privileged materials and prejudicing Sharing Hope. Based on both of its improper subpoena practices, this Court should grant a Protective Order to remedy the prejudice suffered by this Defendant and to discourage any future improper practices.

**B. Sharing Hope is Entitled to a Protective Order Pursuant to Rule 26(c), FRCP to Protect its Peer Review Privileged Materials**

***1. Sharing Hope's Materials and Activities Conducted Under the Auspices of the MPSC's Required Peer Review and Root Cause Analysis Are Protected and Should Not Be Discoverable to Plaintiff***

As discussed *supra*, the federal regulations unique to organ donation provide confidential medical peer review which is protected here. The peer review privilege is a well-recognized process which is protected by the intent of the legislature (as evidenced by state law), the courts, federal regulations governed by OPOs, and public policy. The documents sought by Plaintiff from CMS contain materials which Sharing Hope has sought to protect for the duration of this case because they are self-critical peer review materials which are currently the subject of a properly filed Appeal in the South Carolina Court of Appeals. Here again, as with the recent subpoena issued to CMS in the *Holliman* case, the Plaintiff seeks to make an end-run around the South

Carolina Court of Appeals by seeking materials through another avenue. In this case, asking the Court for clarification that such materials are not privileged. Such efforts should be ceased and the documents containing privileged materials sought from CMS should be protected.

As previously discussed, Sharing Hope and UNOS' MPSC engaged in a retrospective, self-critical quality assurance and peer review evaluation regarding Mr. Patterson's liver transplant following his death. This peer review included consideration of Sharing Hope's collection and reporting of the Donor's medical information. Again, the underlying factual information involving the transplant, including Sharing Hope's contemporaneous records and communications regarding the evaluation of the Donor and the transplant process, have been produced and are not at issue here. It is the communications and materials created *after the transplant* as part of UNOS' mandatory peer review process which are at issue in this appeal.

Sharing Hope has withheld as privileged materials and communications generated during its peer review and has identified the same on its privilege log<sup>14</sup> in the *Holliman* case. Specifically, the withheld materials consist of documents and correspondence exchanged between Sharing Hope (the South Carolina OPO) and the MPSC (the committee established by UNOS as part of its administration of the OPTN) while these entities engaged in their confidential peer review process. To the extent that these communications contain attachments or enclosures of the Donor's medical records, standard operating policies of Sharing Hope, or other records kept in the ordinary course of business, such materials have already been separately produced to the Plaintiff.

*Root Cause Analysis with the Donor Hospital as Peer-Review*

Sharing Hope also engaged in a root cause analysis with the donor hospital, Grand Strand Medical Center, which was conducted to identify the root causes towards a goal of improving

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<sup>14</sup> Discovery in this case is stayed and has been stayed since the filing of initial disclosures

patient safety protocols. One of the documents in issue was prepared and shared with Grand Strand in connection with this root cause analysis. This root cause analysis is also considered a peer-review process, and thus documents generated as a result of the root cause analysis are also protected by the peer-review privilege.

***2. The Portion of Sharing Hope's Peer Review Materials Apparently Provided to CMS Do Not Lose Their Peer Review Protection and Should Not be Used by Plaintiff***

Several of the documents produced by non-party CMS pursuant to the subpoena issued to them without notice to this Defendant were documents which were withheld as privileged on Sharing Hope's privilege log in the related *Holliman* case. Further, the materials claimed as privileged in the *Holliman* case are now a part of an appellate review in South Carolina State Court. This Defendant promptly filed a Motion to Stay the Order Compelling production of Sharing Hope's privileged documents as well as an Appeal in South Carolina State Court System because the result is incompatible with the public policy in South Carolina or any state and because it is illogical that an entity be subject to tort liability for medical malpractice but not be protected from disclosure of its peer review activities, as is any other entity subject to medical malpractice liability. These materials are still privileged, should not have been and would not have been acquired by Plaintiff absent Plaintiff's improper practices and rule violations, and should not be used by Plaintiff.

**CONCLUSION**

For the foregoing reasons, pursuant to Rule 45 and Rule 26(c) of the Federal Rules of Civil Procedure, Sharing Hope respectfully requests that the Court enter an appropriate Protective Order (1) to protect Sharing Hope's peer review privileged materials from further use, dissemination, or function in this case, (2) to remedy the prejudice Sharing Hope has experienced as a result of



Plaintiff's improper acquisition of its protected materials, and (3) to avoid future prejudice to Sharing Hope as a result of the same.

Respectfully submitted,

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**December 23, 2021**  
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